



PATENT
Docket No. 290.00420101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shi et al.)	Group Art Unit:	1617
)		
Serial No.: 09/438,206)	Examiner:	Hui
Confirmation No.: 9018)		
)		
Filed: 12 November 1999)		
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For: METHODS AND COMPOSITIONS FOR TREATING MAMMALIAN SPINAL CORD INJURIES)		

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DECLARATION UNDER 37 C.F.R. § 1.132
OF SCOTT A. SHAPIRO, M.D.

1. I received a B.S. from the University of Illinois (Biology) in 1977. I subsequently received an M.D. from Indiana University in 1981 and joined the neurosurgery faculty as an assistant Professor of Neurosurgery at Indiana University. Since 1987, I have served as resident director of the Neurosurgery residency and am actively involved in resident and medical student education. In 1997 I became Professor of Neurosurgery at Indiana University and am presently the Robert L. Campbell Professor of Neurosurgery. Since 1987, I have also been Chief of Neurosurgery at Wishard Hospital, Attending Neurosurgeon at Roudebush VA Hospital, and a full-time Faculty Neurosurgeon at University and Riley Hospitals, all located in Indianapolis.

2. My expertise is in the areas cranial surgery, spinal surgery and neurosurgical research. I have pioneered novel techniques in cervical spine fusions that have proven to be the most successful techniques with fewest problems and are presently done by the overwhelming majority of spine surgeons in the United States. I have over 70 publications in basic and clinical research in the areas of brain tumors, cerebrovascular disease, spinal fusion, spine surgery, peripheral nerve surgery, and spinal cord injury. In 1996, I had the privilege of operating on Lance Armstrong's brain to remove two tumors and was subsequently featured in his best selling book *It's Not About The Bike*.

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3. I am a diplomat of the American Board of Neurological Surgery, fellow of the American College of Surgeons, member of the American Association of Neurological Surgeons, Congress of Neurosurgeons, Society of Neurological Surgery, Association for Academic Surgery, Joint Spine Section, Joint Cerebrovascular Section, Joint Tumor Section, AMA, ISMA and am former president of the Indiana Neurosurgical Association.

4. I have performed numerous disc surgeries, including lumbar unilateral disc excision operations.

5. Symptoms leading to consideration of a patient for disc surgery include pain, muscle weakness (paresis) and sometimes varying degrees of incontinence. These symptoms are not normally indicative of spinal cord injury.

6. Persons with spinal cord injuries typically present with paralysis and loss of sensation in regions below the level of the spinal injury. These symptoms are not normally associated with disc injury.

7. Disc surgery is not typically performed to treat persons suffering from compression or other contusion of the spinal cord, crushing of the spinal cord or severing of the spinal cord, or any other spinal cord injury.

8. The objective of disc surgery is to remove offending material compressing the peripheral nerve roots. Peripheral nerve roots lie near the spinal cord but do not constitute part of the spinal cord. Contact with the spinal cord during surgery is strictly avoided.

9. Disc surgery, when properly performed, does not result in a compression or other contusion of the spinal cord, crushing of the spinal cord or severing of the spinal cord, or any other spinal cord injury.

10. *Spine Surgery: Techniques, Complication Avoidance and Management*, by Edward C. Benzel (Benzel) is a surgical textbook that is widely respected within the neurosurgical community. Chapters 27 (pp. 369-388) and 28 (pp. 389-400), entitled Thoracic Discectomy and Lumbar Discectomy, respectively, are attached to this Declaration as Exhibit A.

11. Modern surgical techniques employed in disc surgery are minimally invasive and emphasize not touching the spinal cord or even the peripheral nerve roots themselves. Material such as epidural fat and connective tissue that is adjacent to or covers intact nervous tissue is left in place whenever possible, ensuring that continuing procedures involved with removal of disc material do not touch any neural element. Damage to the spinal cord has been essentially

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eliminated due to modern techniques using operating microscopes. Examples stated in Benzel include:

Bone is removed carefully "to allow ensuing visualization of the disc space, usually 3 or 4 mm distance from the rostral edge. During the course of bone removal, the underlying epidural fat is protected." (Benzel, p. 392)

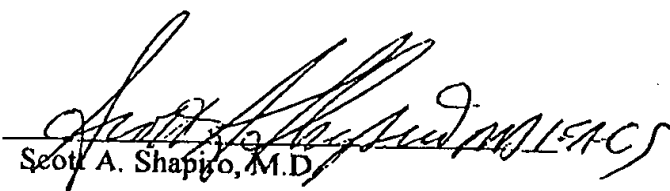
"A reverse angled curette may aid the decompression [of the peripheral nerve root] without manipulating the spinal cord" (Benzel, p. 377)

"The ventral spinal canal and dura mater should be directly inspected subsequent to placement of bone grafts to ensure that there is no encroachment of the spinal canal" (Benzel p. 377)

12. The list of complications in Benzel (Table 27.3, p. 384) following thoracic discectomy, does not even mention spinal cord related symptoms, nor is any "neural" symptom discussed in text entitled "Management of Complications" found in Chapter 28, Lumbar Discectomy (Benzel, pp. 396-399).

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date: 11/14/2002


Scott A. Shapiro, M.D.